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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte RAYMOND IDEKER and GREGORY WALCOTT

Appeal 2008-6033
Application 10/727,123
Technology Center 3700

Decided:[1] March 2, 2009

Before ERIC GRIMES, LORA M. GREEN, and JEFFREY N. FREDMAN, *Administrative Patent Judges*.

GRIMES, *Administrative Patent Judge.*

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a method and system for performing chest compression during CPR. The Examiner

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[1] The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R.§ 1.304, begins to run from the decided date shown on this page of the decision. The time period does not run from the Mail Date (paper delivery) or Notification Date (electronic delivery).

has rejected the claims as obvious. We have jurisdiction under 35 U.S.C. § 6(b). We reverse, but enter a new rejection of two of the claims.

STATEMENT OF THE CASE

The Specification discloses that "[w]hen a subject undergoes cardiopulmonary resuscitation (CPR) for decreased or absent cardiac contraction, arrhythmias (such as ventricular fibrillation) can occur even after initially successful defibrillation or reactivation of the cardiac cycle" (Specification 1). The Specification discloses "devices, methods and computer program products that can allow cardiac compression to be selectively delivered during cardiopulmonary resuscitation and to be timed to a desired portion of an intrinsic spontaneous cardiac cycle and/or an electrical stimulus event to inhibit arrhythmias and/or improve cardiac function" (*id.*).

Claims 26-28, 31-33, 41-45, 49, 51, 52 and 54-57[2] are on appeal. Claim 26 is representative and reads as follows:

Claim 26: A method for performing chest compression during cardiopulmonary resuscitation (CPR), comprising;

sensing a parameter corresponding to a measure of intrinsic spontaneous cardiac activity of a heart in a subject undergoing CPR;

identifying a vulnerable portion of an intrinsic spontaneous cardiac cycle of the subject; and

compressing the heart of the subject during a non-vulnerable portion of the spontaneous intrinsic cardiac cycle based on the identifying step thereby inhibiting reinduction of fibrillation and/or improving cardiac function.

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[2] Claims 29, 30, 34-40, 46-48, 50, 53, 58 and 59 are also pending but have been withdrawn from consideration (Appeal Br. 1).

The claims stand rejected under 35 U.S.C. § 103(a) as follows:

- claims 26-28, 41-43, 49, and 51 based on Gelfand[3] and Link,[4]
- claims 31-33, 44, 45, 52, and 54-57 based on Gelfand, Link, and Halperin.[5]

OBVIOUSNESS

Issue

The Examiner has rejected claims 26-28, 41-43, 49 and 51 under 35 U.S.C. § 103(a) as obvious in view of Gelfand and Link.

The Examiner finds that "Gelfand discloses a method for performing chest compressions where an ECG instrument 123 is employed to sense the intrinsic spontaneous heart activity … [and] compression is applied using a CPR vest 102 that is timed to be delivered at a favorable time to improve cardiac function" (Answer 3). The Examiner finds that Link "discloses that low energy chest wall blows may result in sudden death due to the initiation of ventricular fibrillation (VF)" and "that only blows delivered specifically during the upslope of the T-wave result in VF" (*id.*). The Examiner concludes that "it would have been obvious to one of ordinary skill in the art … to time the compressions to avoid the vulnerable T-wave portion of the cardiac cycle, as suggested by Link, in order to avoid initiating VF in a subject" (*id.* at 4).

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[3] Gelfand et al., US 5,772,613, June 30, 1998.
[4] Link, 81 *Heart* 109-110 (1999). The record copy of Link was apparently printed out from an internet site. Our citations are to the pages of the record copy.
[5] Halperin et al., US 6,390,996, May 21, 2002.

Appellants contend that the combined references would not have suggested avoiding chest compression in CPR during the vulnerable portion identified in Link (i.e., the T wave portion of an ECG) because Gelfand specifically teaches that the time period that follows the QRS portion of an ECG, which includes the T wave portion, is suitable for compression (Appeal Br. 5-6).

The issue with respect to this rejection is: Does the evidence support the Examiner's conclusion that Gelfand and Link suggest a CPR method that avoids compressing the heart during the T-wave portion of the heartbeat?

Findings of Fact

1. Gelfand discloses "a vest-CPR system to increase intrathoracic pressure and intravascular pressure to produce blood flow using a continuous blower to directly pressurize the vest" (Gelfand, col. 3, ll. 20-23).

2. Gelfand discloses that

> [w]hen the vest-CPR system is used to assist a weakened but beating heart, the timing of the vest inflation phase must coincide with the actual heartbeat…. To monitor the heartbeat, an electrocardiogram (ECG) instrument 123 may be used to sense the patient's heartbeat and generate a signal indicative of the heartbeat. The heartbeat signal is used by the timer control circuit 122 to determine when to switch the valve 112 so as to start the vest inflation phase. For example, the timing control circuit 122 may initiate the inflation phase of the vest a predetermined period of time following the QRS complex wave of the ECG signal.

(*Id.* at col. 8, l. 64 to col. 9, l. 8.)

3. Link discloses that "[s]udden death resulting from relatively minor chest wall blows (commotio cordis) has been described in the medical literature since the late 1970s" (Link 1).

4. Link discloses that "[c]ommotio cordis occurs most frequently in baseball, but sudden death owing to chest impact has also been reported in hockey, lacrosse, softball, and after bodily impacts in other sports" (*id.*).

5. Link discloses that, in commotio cordis victims, "the most widely believed mechanism of sudden death is ventricular fibrillation resulting from impact during a vulnerable period of the cardiac cycle" (*id.*).

6. Link discloses an "experimental model of low energy chest wall impact" in which a "30 mph baseball impact was given to the chest wall of anaesthetised juvenile pigs. The impact was gated to the cardiac cycle . . . [and] could be delivered at any chosen time during the cardiac cycle." (*Id.* at 2.)

7. Link discloses that "[i]n this model, ventricular fibrillation was reproducibly initiated by impacts during a 15 ms time window on the upslope of the T wave (30 to 15 ms before the peak of the T wave)" (*id.*).

8. The Specification's Figure 1 is reproduced below.

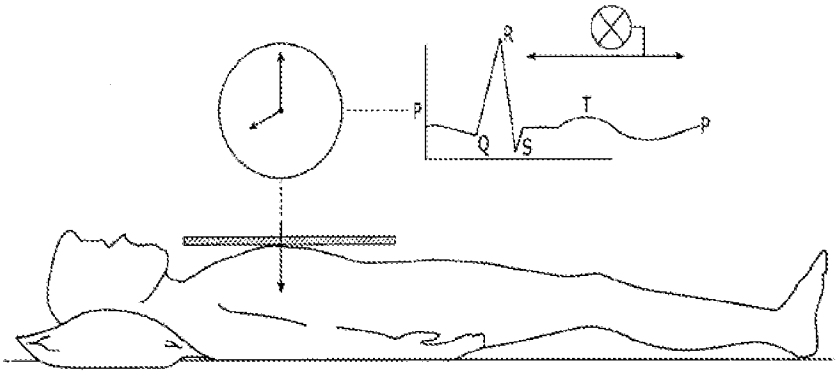

FIG. 1

Fig. 1 is said to show an embodiment in which "cardiac compression can be carried out at a desired time during a particular cardiac cycle" (Spec. 4, ll. 8-10).

9. The Specification discloses that "electrical stimulation can typically only induce ventricular fibrillation during a vulnerable period of the cardiac cycle, which occurs during the T wave portion of the electrocardiogram (shown schematically in Figure 1 as that portion of the cardiac cycle marked with the universal symbol for 'do not', *i.e.*, a circle enclosing 'X' therein)" (*id.* at 6, ll. 25-27).

10. The Specification discloses that Figure 1 shows embodiments in which "cardiac compression [can] be timed to a nonvulnerable period of the cardiac cycle to inhibit the onset of fibrillation and/or increase cardiac function" (*id.* at 6-7).

11. The Specification discloses the compression can be carried out at a time that does not overlap with the T wave portion of a spontaneous intrinsic cardiac cycle (*id.* at 8, ll. 13-15).

Principles of Law

"In rejecting claims under 35 U.S.C. § 103, the examiner bears the initial burden of presenting a *prima facie* case of obviousness. Only if that burden is met, does the burden of coming forward with evidence or argument shift to the applicant." *In re Rijckaert*, 9 F.3d 1531, 1532 (Fed. Cir. 1993).

Analysis

Claim 26 is drawn to a method for performing CPR that entails, among other things, identifying a vulnerable portion of the cardiac cycle and compressing the subject's heart during a non-vulnerable portion of the cardiac cycle. The Specification indicates that a "vulnerable portion" is the T wave portion of the ECG and thus the claimed method entails identifying the T wave portion of the ECG and not compressing the heart during the T wave portion.

Gelfand discloses a vest-CPR system to assist a weakened but beating heart in which the vest inflation phase coincides with the heartbeat. Gelfand also discloses that an ECG instrument may be used to sense the heartbeat and that the inflation phase of the vest may correspond to a predetermined period of time following the QRS complex wave of the ECG signal.

Link discloses that sudden death due to chest impact, such as may happen to baseball players, is likely due to induced ventricular fibrillation. Link also discloses that an experimental model in which a 30 mph baseball impact during the upslope of the T wave of the cardiac cycle reproducibly initiated ventricular fibrillation.

Appellants argue that one of skill in the art would not have found the combined references to suggest avoiding chest compression in CPR during the T wave portion of an ECG because Gelfand specifically teaches that the time period that follows the QRS portion of an ECG, which includes the T-wave portion, is suitable for compression (Appeal Br. 5-6).

We agree with Appellants that the Examiner has not shown that the combined references would have suggested the invention of claim 26. Gelfand specifically discloses that compression be delivered after the QRS portion of the cardiac cycle and, as shown in Figure 1 of the Specification, the T wave portion of the cycle makes up a major portion of suggested period. Link discloses that a baseball impact at 30 mph can cause impact-induced ventricular fibrillation during the rising slope of the T wave. However, the Examiner has not provided a reasonable basis for concluding that a 30 mph baseball impact is comparable to the force of compression delivery during CPR.

Without such a correlation, and in view of the specific teaching in Gelfand that compression be delivered at point after the QRS waves, the Examiner has not adequately explained why one of skill in the art would have been motivated to combine the references to arrive at the claimed invention; it is not clear from the references what relevance the baseball impact study has to the compression device and method of Gelfand. Thus, in absence of a correlation between typical CPR compression forces and the force of baseball impact in Link, the Examiner has not met the initial burden of establishing a prima case of obviousness in accord with *In re Rijckaert*.

Claims 27, 28, 41-43, and 52 also stand rejected as obvious in view Gelfand and Link. Like claim 26, each of claims 27, 28, 41-43, and 52 requires avoiding chest compressions during a vulnerable portion of the cardiac cycle. However, for the reasons discussed above with respect to claim 26, the Examiner has not adequately explained why one of skill in the art would have been motivated to combine Gelfand and Link to arrive the claimed inventions.

The Examiner has also rejected claims 31-33, 44, 45, 52 and 54-57 under 35 U.S.C. § 103(a) as obvious in view Gelfand, Link and Halperin. Each of the rejected claims depends on a claim that requires avoiding chest compressions during a vulnerable portion of the cardiac cycle. The Examiner relies on the combination of Gelfand and Link as discussed above, and finds that Halperin suggests limitations in the dependent claims. Thus, for the reasons discussed above, the Examiner has not adequately explained why one of skill in the art would have been motivated to combine the cited references to arrive the claimed inventions.

Conclusions of Law

The evidence does not support the Examiner's conclusion that Gelfand and Link suggest a CPR method that avoids compressing the heart during the T-wave portion of the heartbeat.

NEW GROUND OF REJECTION

Under the provisions of 37 CFR § 41.50(b), we enter the following new ground of rejection: claims 41 and 42 are rejected under 35 U.S.C. § 102(b) as anticipated by Gelfand.

Claims 41 and 42 read as follows:

Claim 41: A system for performing chest compression during cardiopulmonary resuscitation (CPR), comprising;

means for sensing a parameter corresponding to a measure of intrinsic spontaneous cardiac activity of a heart in a subject undergoing CPR; and

means for electronically identifying a favorable time to compress the chest to avoid a vulnerable portion of a spontaneous intrinsic cardiac cycle of the subject based on the sensed parameter; and

means for compressing the heart of the subject during a non-vulnerable portion of the intrinsic cardiac cycle based on the identified time.

Claim 42: A system for assisting in chest compression in a subject having cardiomalfunction, comprising:

at least one cardiac activity sensor in communication with the heart of a subject configured to detect a cardiac activity parameter; and

a controller in communication with the at least one cardiac activity sensor,

wherein, in operation, the at least one cardiac activity sensor transmits data to the controller regarding a spontaneous intrinsic cardiac cycle of the subject and the controller identifies a favorable time to deliver a chest compression based on the transmitted sensor data to avoid a vulnerable portion of the spontaneous intrinsic cardiac cycle.

Findings of Fact

12. The Specification discloses that the compression means may be an inflatable vest (Spec. 10, ll. 27-30).

13. The Specification discloses that the means for sensing a parameter corresponding to a measure of intrinsic spontaneous cardiac activity may be provided by an electrocardiogram signal (*id.* at 8, ll. 21-22).

14. The Specification discloses that the means for electronically identifying a favorable time to compress the chest may be an electrocardiographic machine "configured to incorporate cardiocompression

timing to provide the cardiocompression alert signal … and/or direct activation of mechanical devices" (*id.* at 10, ll. 16-18).

Principles of Law

"To anticipate a claim, a reference must disclose every element of the challenged claim and enable one skilled in the art to make the anticipating subject matter." *PPG Indus. Inc. v. Guardian Indus. Corp*, 75 F.3d 1558, 1566 (Fed. Cir. 1996).

Construing a means-plus-function limitation requires determining "what structures have been disclosed in the specification that correspond to the means for performing that function." *Kemco Sales, Inc. v. Control Papers Co.*, 208 F.3d 1352, 1361 (Fed. Cir. 2000).

"[T]he patentability of apparatus or composition claims depends on the claimed structure, not on the use or purpose of that structure." *Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 809 (Fed. Cir. 2002).

"It is well settled that the recitation of a new intended use for an old product does not make a claim to that old product patentable." *In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997).

Analysis

Claim 42 is directed to a system, or apparatus, for assisting in chest compression, comprising a cardiac activity sensor in communication with a controller capable of identifying a favorable time to deliver chest compression based on the sensor data.

As discussed above, Gelfand discloses a compression vest for use in a patient having cardiomalfunction that is used in conjunction with an electrocardiogram (ECG) instrument to monitor the heartbeat such that the heartbeat signal is used by the timer control circuit to determine when to deliver compression, i.e. inflate the vest. Thus, Gelfand discloses the claimed apparatus comprising a cardiac activity sensor and controller for identifying a favorable time to deliver chest compression based on the sensor data.

Claim 42 also contains a "wherein" clause stating that "in operation, the at least one cardiac activity sensor transmits data to the controller regarding a spontaneous intrinsic cardiac cycle of the subject and the controller identifies a favorable time to deliver a chest compression based on the transmitted sensor data to avoid a vulnerable portion of the spontaneous intrinsic cardiac cycle." However, the claim is directed to an apparatus, not a method of using an apparatus. Claim 42's "wherein" clause merely recites the intended use of the claimed apparatus, and therefore the claim reads on any apparatus that is *capable* of being used as recited. Gelfand's system reasonably appears to be capable of carrying out the operation recited in claim 42's "wherein" clause even if it is not disclosed as being used that way.

Claim 41 is drawn to a system, or apparatus, for performing chest compression during CPR that comprises (i) means for sensing a parameter of intrinsic spontaneous cardiac activity of a heart, (ii) means for electronically identifying a favorable time to compress the chest, and (iii) means for compressing the heart. The Specification discloses that the sensing means

may be an ECG machine, that the means for electronically identifying a favorable time for compression may by an ECG machine configured to provide this function, and that the compressing means may be an inflatable vest. As set forth above, Gelfand discloses an ECG machine to sense heartbeat and configured to identify a favorable time to deliver compression, and Gelfand discloses an inflatable vest as a compression device. Thus, Gelfand discloses a system having all of the elements recited in claim 41.

We have applied the new ground of rejection only to independent claims 41 and 42. We leave it up to the Examiner, who has more expertise in this area, to determine whether the rejection should be applied to any of the other pending claims.

SUMMARY

The rejection of claims 26-28, 41-43, 49 and 51 under 35 U.S.C. § 103(a) in view of Gelfand and Link and the rejection of claims 31-33, 44, 45, 52 and 54-57 under 35 U.S.C. § 103(a) in view of Gelfand, Link, and Halperin are reversed.

A new ground of rejection of claims 41 and 42 under 35 U.S.C. § 102(b) as anticipated by Gelfand is set forth.

TIME PERIOD FOR RESPONSE

This decision contains a new ground of rejection pursuant to 37 C.F.R. § 41.50(b) (effective September 13, 2004, 69 Fed. Reg. 49960 (August 12, 2004), 1286 Off. Gaz. Pat. Office 21 (September 7, 2004)). 37 CFR § 41.50(b) provides "[a] new ground of rejection pursuant to this paragraph shall not be considered final for judicial review.

37 C.F.R. § 41.50(b) also provides that the appellant, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of the appeal as to the rejected claims:

> (1) *Reopen prosecution*. Submit an appropriate amendment of the claims so rejected or new evidence relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the proceeding will be remanded to the examiner . . . .
>
> (2) *Request rehearing*. Request that the proceeding be reheard under § 41.52 by the Board upon the same record . . . .

REVERSED, 37 C.F.R. § 41.50(b)

dm

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